

**From:** Ed & Emma Stamas <estamas@mtdata.com>  
**To:** <VermontYankeeEIS@nrc.gov>  
**Date:** Fri, Feb 2, 2007 3:58 PM  
**Subject:** Comments

Attached are comments reagrding the renewla of Vermont Yankee Nuclear facility.

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MESSAGE	93	Friday, February 2, 2007 3:58 PM
TEXT.htm	799	
VermontYankee .doc	31744	
TEXT.htm	752	
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I am recently retired as Director of Quality Assurance for a major Pharmaceutical firm. My department was responsible for inspecting all of our plants worldwide for compliance to FDA regulations. While this industry is not the same as the nuclear industry, I feel there are similar issues that could be related.

During my many years in Quality Assurance, I realized that quality cannot be inspected into a facility. If there were systematic problems they would still be there after the inspection team left. No inspection team, however proficient, can inspect 100% of every system. At best you are inspecting a small percentage of random components that hopefully gives a true representation of the entire system. I have seen plants pass internal inspections with glowing reports, only to be shut down by FDA inspectors within six months of the initial inspection. I have also seen our internal plant inspectors provide me with a list of major deficiencies, each capable of causing a plant shutdown due to possible contamination. But before we had a chance to correct them, the FDA would send in their team, only to give us a clean bill of health and permission to continue to manufacture pharmaceuticals for human consumption. At that point, it would be the responsibility of the plant to openly admit to FDA inspectors that it had overlooked several critical system deficiencies. However, too often, the temptation is to keep silent and let money and greed make our decisions. My responsibility was to assure that our plants were meeting FDA regulations so when the FDA came in to inspect, there would be no problems. In my experience, this was futile. A team of inspectors with fresh, unbiased eyes always had the advantage over the internal inspection team and in some cases, I admit not all, they found major issues that were overlooked by the plant inspection team.

Based on the above comments, I have the following questions for the NRC as related to the renewal of the Vermont Yankee Facility:

1. How do you plan to assure that any upgrades, retrofits or system componentry changes to the exiting system will not have a detrimental effect on another system which may then become a major problem that was overlooked by inspectors?
2. How will you ensure that inspections are carried out not only by well trained, experienced individuals, but by teams that are unbiased and looking at things without prior observations creating a mindset that everything is OK?
3. How can you be sure that your quality inspections are looking at 100% of every plant system. If you admit that they are not, how can you justify using a random inspection as being representative of the entire facility?
4. And finally, how will you guarantee to the public, that if the Vermont Yankee is given a 20 year renewal, that we will be assured of honest decisions related to these inspections and not let greed, money and jobs interfere with the truth?

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